510(K) SUMMARY

JAN 2 3 2009

This summary of 510(K) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807 92

The assigned 510(k) number is K083176

Manufacturer:

CHAMPAK ENTERPRISE CO , LTD
27-1, Jhaiming St , Dasi Township,
Taoyuan County, 335,
Taiwan (R O C)

Official Correspondent:

Lloyd Soong
President & CEO
Pasture Pharma Pte, Ltd
8 Boon Lay Way #04-01
Trade Hub 21, Singapore 609964

US agent and correspondent:

Mrs Sarah Hassan
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Murrieta, CA 92563 USA
Tel 8603715604
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Date of Submission:

OCT/20/2008

Classification name:

Filtering Facepiece Respirator for Use by the General Public in Public Health Medical Emergencies Class II

Proprietary Name:

Pasture™ F550G & A520G Respirators

Common name:

Filtering Facepiece Respirator for use by the general public in public health medical emergencies

Regulatory Reference:

21 CFR 880 6260

Predicate Device:

3M 8612F & 8670F

K083176

Filtering Facepiece Respirator for Use by the General Public in Public Health Medical Emergencies
K062070

Labels/ Labeling:

This device will be marketed NIOSH-certified N95 respirator for use by the general public in public health medical emergencies for the Intended Use purpose below

Intended Use:

This device is intended for use by the general public in public health medical emergencies

Device Description:

Pasture F550G respirator is a duck bill mask as described in NIOSH N95 standard It is in 5 layers and composed of spunbond, meltblown and polyester, also with nose cushion, elastic loops and/or strip and nosepiece which is the combination of zinc wires and embedded polyester inside of layers

Pasture A520G respirator is a cone shaped mask as described in NIOSH N95 standard It is in 4 layers and composed of spunbond, meltblown and polyester, also with synthetic rubber band which is coated with polyester and free of latex

Comparison to Predicated Devices:

F550G and A520G are substantially equivalent in safety and effectiveness compared to 3M 8612F and 8670F respirators for the same intended use

	Predicate (3M)	F550G	A520G
Intended Use	For use by general public in public health emergencies	Same	Same
NIOSH Certification	N95 TC-84A-4516	N95 TC84A-4665	N95 TC84A-4664
Fluid resistant	Yes	yes	Yes
Fit Assessment Test	done	done	Done
Biocompatibility Test		Cytotoxicity	Cytotoxicity
	Dermal sensitization	Dermal sensitization	Dermal sensitization
	Skin irritation	Skin irritation	Skin irritation

Conclusions:

F550G and A520G have the same intended use as the predicate devices The test data submitted in this submission demonstrate that the subject devices are as safe and effective as the predicate and technological characteristics do not raise any new questions of safety and effectiveness F550G and A520G are substantially equivalent to the 3M respirators cleared in K062070

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Pasture Pharma PTE Limited
C/o Ms. Sarah Hassan
US Medpharm
29266 Via Fronter
Murrieta, California 92563

JAN 23 2009

Re: K083176
Trade/Device Name: Pasture™ A520G & Pasture™F550G Respirators
Regulation Number: 21 CFR 880.6260
Regulation Name: Respirator, N95, for Use by the General Public in Public Health Medical Emergencies
Regulatory Class: II
Product Code: NZJ
Dated: January 15, 2009
Received: January 15, 2009

Dear Ms. Hassan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K 083176

Device Name: Pasture™ A520G & Pasture™F550G

Indications for Use:

This device is a disposable filtering facepiece respirators intended for use by the general public in public health medical emergencies – Pasture™ A520G Respirator and Pasture™ F550G Respirator
Not designed for children.

Prescription Use____ OR Over-The-Counter-Use__X__

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K083176